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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/31/2003

Eric Hammill

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9309

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EXAMINER

STOKLOSA, JOSEPH A

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

12/04/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com

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Office Action Summary	Application No. 10/698,843	Applicant(s) HAMMILL ET AL.	
	Examiner JOSEPH STOKLOSA	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 24-35 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 24-35 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 9-10, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Carner (US 6,253,111).

3. Carner discloses a multi-lumen and multi conductor lead system comprising; a lead body (e.g. lead body 22), a conductor disposed within the insulation layer and at least one impedance monitoring conductive sleeve. Examiner considers the first outer conductive tubing disclosed by Carner for electrically and mechanically connecting to sensor 60, to be the impedance monitoring sleeve which will have a first impedance in a first, un-breached, condition and a second impedance value in a second, breached, condition. Carner discloses the first conductive tubing to have a diameter slightly less than the lead body diameter and greater than the second and third conductors that connect to distal pacing/stimulation electrodes (e.g. Col. 3, line 21-42).

4. It is further of note that applicant is claiming one conductor and one electrode; Therefore Examiner has considered any additional conductors disclosed by Carner to be impedance monitoring conductive sleeves.

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5. With regard to claim 3, Carner discloses lead wear may create an opening through the lead body insulation to the conductive sleeve (e.g. Col. 3, line 36-37).

6. With regard to claim 5, Carner discloses at least a third conductive sleeve disposed within the insulating layer and isolated from the first electrode (e.g. Fig. 2).

7. With regard to claim 9, Carner discloses the system to include a pulse generator for delivering stimulation therapy (e.g. Col. 2, line 65).

8. With regard to claim 10, Carner discloses the first conductive sleeve may be connected to a sensor unit (e.g. Col. 3, line 5-20).

Claim Rejections - 35 USC § 102/103

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that

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the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 24, 26-29, 32-33, 35, and 38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carner as applied above.

13. With regard to claim 24, Carner discloses the invention as claimed including a connector for electrically and mechanically connecting the impedance monitoring conductive sleeve to a sensor and the IMD housing. Carner is silent to the connecting the impedance monitoring conductive sleeve to an impedance monitoring sensor; however It is also of note that the impedance monitoring device has been inferentially included, and not positively recited, and only requires a connector sized and shaped that is capable of connecting to an impedance monitoring device. Accordingly, Examiner considers Carner to meet this limitation as it meets all structural limitations and would be capable of connecting the conductive sleeve to an impedance monitoring device as well.

14. In the alternative it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Carner with a connector for electrically and mechanically connecting the

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impedance monitoring conductive sleeve to an impedance monitoring device since such a modification would provide the predictable results of determining lead fracture which Carner acknowledges as a problem of implantable lead systems.

15. With regard to claim 38, Examiner considers the continuous conductive sleeve disclosed by Carner to necessarily include a plurality of discrete conductive elements where each atom of the conductive sleeve is a discrete conductive element in its own.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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18. Claims 6-8 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carner as applied above.

19. Carner discloses the invention as claimed but fails to explicitly teach a second conductive sleeve/conducting tube that will surround the conductor and the second conductive sleeve surrounding a second conductor. Examiner considers Carner to disclose the basic principle of surrounding a conductor with an outer conductive tube and insulation in between for preventing loss of function of the stimulation lead in cases of lead fracture and breach (e.g. Col. 3, line 36) and therefore it would have been obvious to one having ordinary skill in the art to modify the system as disclosed by Carner with using a second conductive sleeve/conducting tube that will surround the conductor and the second conductive sleeve surrounding a second conductor, since such a modification would provide the predictable results of providing for at least the same precautions in a bipolar configuration and enabling lead function and identifiable lead fracture/breach detection.

Response to Arguments

20. Applicant's arguments with respect to claims 1-10, 24, 26-35, and 38 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

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See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

Joseph Stoklosa
Examiner
Art Unit 3762

/Joseph Stoklosa/
Examiner, Art Unit 3762
11/25/2009